Prescribing Information: Vaxelis® suspension for injection in pre-filled syringe.
Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Single dose of vaccine supplied in a pre-filled syringe. One dose of 0.5ml contains Diphtheria Toxoid (≥20 IU), Tetanus Toxoid (≥40 IU), Pertussis Toxoid (20µg), Filamentous Haemagglutinin (20µg), Pertactin (3µg), Fimbriae Types 2 and 3 (5µg), Hepatitis B surface antigen (10µg), Poliovirus (Inactivated) (Type 1 (Mahoney) (40 D antigen units), , Type 2 (MEF-1) (8 D antigen units), Type 3 (Saukett) (32 D antigen units)), and *Haemophilus influenzae* type b polysaccharide ((Polyribosylribitol Phosphate) (3µg) conjugated to meningococcal protein (50µg)).
Indication: Vaxelis (DTaP-HB-IPV-Hib) is indicated for primary and booster vaccination in infants and toddlers from the age of 6 weeks, against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by *Haemophilus influenzae* type b (Hib). The use of Vaxelis should be in accordance with official recommendations.
Dosage and Administration: The primary vaccination schedule consists of two or three doses, with an interval of at least 1 month between doses, and may be given from 6 weeks of age, in accordance with the official recommendations. Where a dose of hepatitis B vaccine is given at birth, Vaxelis can be used for supplementary doses of hepatitis B vaccine from the age of 6 weeks. If a second dose of hepatitis B vaccine is required before this age, monovalent hepatitis B vaccine should be used. Vaxelis can be used for a mixed hexavalent/pentavalent/hexavalent combined vaccine immunisation schedule. After a 2-dose or a 3-dose primary series vaccination with Vaxelis, a booster dose should be given at least 6 months after the last priming dose. Vaxelis may be used as a booster dose in children who received another hexavalent vaccine for their primary series. When a booster dose with a hexavalent DTaP (diphtheria, tetanus, and acellular pertussis) containing vaccine is not available, a dose of Hib vaccine must be administered, as a minimum.
Vaxelis should only be administered by intramuscular (IM) injection. The recommended injection sites are the anterolateral area of the thigh (preferred site for infants under one year of age) or the deltoid muscle of the upper arm. *Paediatric population:* The safety and efficacy of Vaxelis in infants less than 6 weeks of age have not been established. No data are available in older children. **Contraindications**: History of an anaphylactic reaction after a previous administration of Vaxelis or a vaccine containing the same components or constituents. Hypersensitivity to the active substances or to any of the excipients or to trace residuals (glutaraldehyde, formaldehyde, neomycin, streptomycin, polymyxin B, and bovine serum albumin). Encephalopathy of unknown aetiology, occurring within 7 days following prior vaccination with a pertussis containing vaccine. In these circumstances, pertussis vaccination should be discontinued, and the vaccination course should be continued with diphtheria, tetanus, hepatitis B, poliomyelitis, and Hib vaccines. Uncontrolled neurologic disorder or uncontrolled epilepsy: pertussis vaccination should not be administered until treatment for the condition has been established, the condition has stabilised, and the benefit clearly outweighs the risk.
Precautions and Warnings: Vaxelis will not prevent disease caused by pathogens other than *Corynebacterium diphtheriae*, *Clostridium tetani*, *Bordetella pertussis*, hepatitis B virus, poliovirus or *Haemophilus influenzae* type b. Hepatitis D does not occur in the absence of hepatitis B infection, so it is not expected after immunisation. Vaxelis will not protect against hepatitis infection caused by other agents such as hepatitis A, hepatitis C and hepatitis E or by other liver pathogens. Vaxelis does not protect against disease caused by *Haemophilus influenzae* other than type b or by other microorganisms that cause invasive disease such as meningitis or sepsis, including *N. meningitidis*. As with any vaccine, a protective immune response may not be elicited in all vaccines. Vaccination should be preceded by a review of the individual's medical history. Appropriate medical treatment and supervision should be readily available in case of a rare anaphylactic reaction. Administration of Vaxelis should be postponed in children suffering from moderate to severe acute disease, with or without fever. The presence of a minor illness and /or low-grade fever does not constitute a contraindication. The decision to continue administering a pertussis-containing vaccine should be carefully considered if any of the following events have occurred after a previous pertussis vaccine: Temperature of ≥40.5°C within 48 hours, not attributable to another identifiable cause; Collapse or shock-like state (hypotonic-hyporesponsive episode [HHE]) within 48 hours of vaccination; Persistent crying lasting ≥3 hours, occurring within 48 hours of vaccination; Convulsions with or without fever, occurring within 3 days of vaccination. There may be some circumstances, such as high incidence of pertussis, when the potential benefits outweigh possible risks. If Guillain-Barré syndrome has occurred within 6 weeks of receipt of prior vaccine containing tetanus toxoid, the decision to give any vaccine containing tetanus toxoid, including Vaxelis, should be based on careful consideration of the potential benefits and possible risks. A history of febrile convulsions, a family history of convulsions, or Sudden Infant Death Syndrome (SIDS) do not constitute a contraindication for the use of Vaxelis. Individuals with a history of febrile convulsions should be closely followed up as febrile convulsions may occur within 2 to 3 days post vaccination. Do not administer by intravascular, intradermal or subcutaneous injection. When Vaxelis is co-administered with pneumococcal conjugate vaccine (PCV13), the rate of fever is higher following the booster dose in the second year of life compared to the primary series. Premature infants: Based on limited data of 111 pre-term infants Vaxelis can be given to premature infants. The immune responses to Vaxelis in these infants were generally similar to those of the overall study population. However, a lower immune response may be observed, and the level of clinical protection is unknown. When administering the primary immunisation series to premature infants (born ≤28 weeks of gestation) there is potential risk of apnoea and the need for 48-72 hours of respiratory monitoring, particularly for those with history of respiratory immaturity should be considered. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed. Genetic Polymorphism: Immune responses to the vaccine have not been studied in the context of genetic polymorphism. Immunocompromised children: The immunogenicity of the vaccine may be reduced by immunosuppressive treatment or immunodeficiency. It is recommended to postpone vaccination until the end of such treatment or disease. Nevertheless, vaccination of individuals with chronic immunodeficiency such as HIV infection is recommended even if the antibody response may be limited. Blood disorders: As with all injectable vaccines, the vaccine must be administered with caution to individuals with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration. Interference with laboratory testing: Since the Hib capsular polysaccharide antigen is excreted in the urine, a false positive urine test can be observed using sensitive tests, for at least 30 days following vaccination. Other tests should be performed in order to confirm Hib infection during this period**.** Sodium: This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'
Interactions: Vaxelis may be administered simultaneously with pneumococcal polysaccharide conjugate vaccines, rotavirus vaccines, measles, mumps, rubella (MMR) and varicella containing vaccines**,** meningococcal B and C conjugate vaccines. Data from a clinical study indicate that, when Vaxelis is co-administered with pneumococcal conjugate vaccine (PCV13), the rate of fever is higher following the booster dose in the second year of life compared to the primary series. Almost all fevers were mild or moderate (<39.5°C) and transient (duration of ≤2 days). Co-administration of Vaxelis with other injectable vaccines must be carried out at separate injection

sites and, preferably, separate limbs. Vaxelis should not be mixed with any other vaccine or other parenterally administered medicinal products. Immunosuppressive therapy may interfere with the development of expected immune response. Due to an increased risk of fever, tenderness at the injection site, change in eating habits and irritability when a different hexavalent vaccine with a similar reactogenicity profile to Vaxelis was co-administered with Meningococcal B vaccine, separate vaccinations can be considered. **Fertility, pregnancy & lactation**: This vaccine is not intended for administration to women of child-bearing potential.

Adverse Reactions: *Very common (≥1/10):* decreased appetite, somnolence, vomiting, injection site (erythema, pain & swelling), crying, pyrexia, irritability. *Common (≥1/100 to <1/10):* diarrhoea, Injection site bruising, induration and nodule. *Serious – frequency not known:* Convulsions with or without fever and hypotonic-hyporesponsive episode (HHE). *Rare:* hypersensitivity and anaphylactic reaction, extensive swelling of vaccinated limb. Prescribers should consult the SmPC in relation to other adverse reactions.

List Price: £45.31 for 1 syringe **Legal Category:** POM

Marketing Authorisation Number: PLGB 50692/0001

Marketing Authorisation Holder: MCM Vaccine B.V. Robert Boyleweg 4, 2333 CG Leiden, The Netherlands.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to UK-drugsafety@sanofi.com